REMARKS

Claims 1-22 have been cancelled without prejudice.

New claims 23-34 have been added to replace claims 11-22 and represent a modified version of the prior claims.

The new claims are fully supported by the specification as originally filed and are deemed to be free of formal defects.

The Examiner's objections and rejections are addressed below.

Claim objections

The objection to prior Claim 11 has been obviated in new claim 23, wherein "laminarin" is correctly written.

Rejection under 35 USC §112

Claims 11-22 are rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Examiner, the phrase "a chemotherapeutic antineoplastic treatment for cancer" in claim 11, is a phrase which renders the claim indefinite, the Examiner considering that it is unclear whether this treatment actually treats cancer or how this treatment is related to treating cancer.

Without addressing the merits of this objection, in new claim 23, the words "for cancer" are deleted in the said phrase.

Actually, a "chemotherapeutic antineoplastic treatment" is intended to treat cancers or tumors.

Claims 11-22 are also rejected under 35 USC §112, the Examiner stating that the specification

> *".... while being enabling for the promote of the regeneration of the cells in the bone marrow and the peripheral blood of a patient which cells undergo an acute reduction due to the effect of the antineoplastic agent, cyclophosphamide, comprising the administration of a composition composition comprising cyclophosphamide and laminarin, does not reasonably provide enablement for the treatment of cancer in a patient."*

Applicants note in particular that the Examiner acknowledges that the specification enables the promotion of the regeneration of the cells which undergo an acute reduction due to the effect of antineoplastic agents.

Applicants also note that the Examiner alleges that the same specification does not reasonably provide enablement for the treatment of cancer in a patient. Justification for his position is provided by the Examiner from page 2 to page 8 of the action.

Applicants do not necessarily dispute this position of the Examiner.

However, Applicants respectfully traverse that rejection under 35 USC §112 based on the fact that the specification does not provide enablement for the treatment of cancer.

Actually, the object of the instant invention is not to provide a treatment of cancer by way of chemotherapeutic antineoplastic treatments using antineoplastic agents.

Chemotherapeutic antineoplastic treatments as well as antineoplastic agents commonly called "chemotherapy" drugs or agents are well-known for many years by those skilled in the art. In that respect, in Table I, on pages 1, 2 and 3 of the specification are listed 57 well-known chemotherapeutic drugs. These chemotherapeutic drugs have been commercialized for many years.

For instance, chemotherapeutic drugs based on cyclophosphamide are marketed in France since 1960 under the trademark "ENDOXAN" ; they are marketed in the USA under the trademarks "CYTOXAN" and "NEOSAR" and in Canada under the trademarks "CYTOXAN" and "PROCYTOX". Additionally, the particulars of the chemotherapeutic antineoplastic treatments carried out using these drugs are also well-known by those skilled in the art.

They are thus not part of the instant invention whose object is to combat one particular side effect of "chemotherapy" agents, i.e. the acute reduction they induce in the patient of the number of cells, especially granulocytes, through promotion or acceleration of the regeneration of these cells which is achieved by administration of laminarin, keeping in mind that the reduction of granulocytes renders the patient sensitive against infections until regeneration of the cells is completed.

The newly presented claims 23-34 are deemed to thus provide a more accurate description to the present invention, and the Examiner himself has already acknowledged that the promotion of the regeneration of the cells in question in the bone marrow and in the peripheral blood is enabled by the specification.

In consequence, the rejection under 35 USC §112 is respectfully traversed and should be withdrawn.

Rejection under 35 USC §103

Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Luzio et al. in view of Yvin et al. (US 2003/0119780 A1).

According to the Examiner, Di Luzio et al. disclose a method comprising the administration of an effective amount of a particular antineoplastic agent, i.e. cyclophosphamide, for the treatment of tumors (cancer) in rats (see abstract) ; furthermore, Di Luzio et al. disclose a method comprising the administration of an effective amount of an antineoplastic agent (cyclophosphamide) in conjunction (combination) with an effective amount of a β-1,3 glucan (CAS # 9012-72-0) to rats (see abstract). Applicants do not contest these arguments.

Still according to the Examiner,

- the difference between applicants' claimed method and Di Luzio et al.'s method is that Di Luzio et al. do not use laminarin and
- Yvin et al. disclose a method treating cancer growth (tumor growth) comprising the administration of an effective amount of soluble laminarin to mice (see page 4, sections [0094] to [0099]).

Again, Applicants do not contest these points.

The Examiner concludes that it would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Di Luzio et al. and Yvin et al., to have used the method of Di Luzio et al. to prepare a composition comprising a combination of an antineoplastic agent such as cyclophosphamide and laminarin to treat cancer (tumors).

However, the object of the instant invention is not to provide a combination of an antineoplastic agent such as cyclophosphamide and laminarin to treat cancer but a method for promoting the regeneration of cells, in other words to combat, by using laminarin, the side effect consisting in the acute reduction of the cells due to the action of the antineoplastic agent. Indeed, the capability of laminarin to promote regeneration of the cells was absolutely surprising and unexpected and could in no case be derived from the knowledge of both prior art references.

The Examiner further considers that this is an inherent effect of laminarin, and Applicants respectfully disagree with this conclusion.

In particular, Yvin et al. does not teach the use of an antineoplastic agent and therefore no acute reduction of the number of cells occurs in connection with the experiences disclosed in Yvin et al.

Thus, no regeneration of the cells could be promoted, as no reduction of the number of the same cells took place.

Thus, there is no inherent anticipation on the basis of Yvin, and none of the cited references disclose or suggest the invention as presently claimed.

From the foregoing remarks, it is clear that the instant invention as defined in the new claims is not only novel but also unobvious over the cited prior art. Thus, the Examiner's rejection under 35 U.S.C. §103 on the basis of the cited references is respectfully traversed and should be withdrawn.

In view of the above amendments and remarks, Applicants respectfully submit that the claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. Should the Examiner believe that a discussion with the undersigned counsel would expedite prosecution of the application, a telephone call to (703) 739-4900 would be welcomed.

Respectfully submitted,

Dated: September 11, 2006 By: 

B. Aaron Schulman
Reg. No. 31,877

STITES & HARBISON PLLC
1199 N Fairfax Street,
Suite 900
Alexandria, VA 22314
(703) 739-4900